DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 6, 2015

Sensible Medical Innovations Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1835 Market St
Suite 2920
Philadelphia, Pennsylvania 19103

Re: K150095
Trade/Device Name: ReDS™ Wearable System
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: July 8, 2015
Received: July 8, 2015

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K150095

Device Name

ReDS™ Wearable System

Indications for Use *(Describe)*

ReDS is intended for use by qualified health care practitioners and by patients, under the direction of a physician, in hospitals, hospital-type facilities and home environment, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

ReDS is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Recovering from Coronary Artery Disease related event

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY

DATE PREPARED: July 24, 2015

ReDS Wearable System

510(k) Number: K150095

Applicant's Name:

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Device Trade Name:

ReDS Wearable System

Common/Classification Name:

Impedance plethysmograph

Classification:

FDA has classified impedance plethysmographs as Class II devices (product code DSB, 21 CFR 870.2770), and they are reviewed by the Cardiovascular panel.

Predicate Devices:

- ZOE Fluid Status Monitor (NMT Medical), product code DSB, cleared for marketing under K131509, K112830, K042113, K133301 (primary predicate)
- Aesculon (Osypka Medical), product code DSB, cleared for marketing under K070985, K081035

Indications for Use:

ReDS is intended for use by qualified health care practitioners and by patients, under the direction of a physician, in hospitals, hospital-type facilities and home environment, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

ReDS is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Recovering from Coronary Artery Disease related event

Device Description:

The ReDS Wearable System ("ReDS") is a non-invasive thoracic base wave impedance monitor that provides measurement of patient lung fluid content. ReDS™ technology measures wave impedance of biological tissues. Low power electromagnetic (EM) signals are emitted into the body, and intercepted by sensors on the body. The wave impedance is a function of the distributed tissue conductivity and capacitance properties, and is representative of tissue fluid content.

The system consists of a Wearable Vest connected to a bedside console, as well as a cloud application. The Wearable Vest encases two sensors and an attachment mechanism. The Bedside Console is an enclosure housing the electronic modules, an embedded computer and a touch-screen display. The device software provides the management of the device as well as analysis of the measured signals, graphic display of readings, reporting, and communications functionality to enable remote patient monitoring.

Technological Characteristics:

The ReDS Wearable System's technological characteristics are substantially equivalent to those of its predicate devices. All of the devices are non-invasive, prescription use, transportable bedside devices indicated for use in hospital and hospital-like environments by healthcare providers, and both the ReDS and the Aesculon are also indicated for use in the home environment by patients for self-measuring. Same as both predicates, ReDS uses non-invasive measurements of impedance characteristics to assess the amount of fluid in tissue. All of the devices use sensing elements placed on the user's body and measurement

initiation through a graphical user interface. ReDS sensors are embedded in the wearable vest, whereas the predicate devices use sensors adhered to the body. The minor differences between the ReDS and the predicate devices, e.g., range of parameters, number of sensors, and the sensor placement methods, do not raise new types of safety and effectiveness questions. These differences have been assessed in bench, preclinical, and clinical testing. Results established that the ReDS System performs as intended and is substantially equivalent to its predicate devices.

Performance Data:

The ReDS Wearable System was evaluated in non-clinical, preclinical, and clinical testing. Results demonstrated that the device meets specifications and supported substantial equivalence to the predicate devices. The device is not provided sterile and does not require end user sterilization.

Biocompatibility

ISO 10993 testing demonstrated biocompatibility of the device materials. Cytotoxicity (ISO 10993-5), intracutaneous (ISO 10993-10), and sensitization (ISO 10993-10) testing demonstrated all passing results, supporting the biocompatibility of the device for its intended use.

Software

Software validation and verification testing was conducted for the ReDS System software. Results demonstrated that the software was appropriate for release. The software hazard analysis was performed in accordance with ISO 14971:2007.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing were conducted. Results demonstrated that the system complies with the applicable testing standards (IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60601-1-6, and IEC 62366).

Bench Testing

Bench testing, demonstrating substantial equivalence to the predicate devices, provided display parameter validation (repeatability, reproducibility and accuracy), mechanical durability and EM signal specifications verification. Usability testing was also conducted to validate use of the system by the intended professional and lay users. All performance testing passed according to defined acceptance criteria, demonstrating that the device performs as expected.

Animal Study

The ReDS System was also evaluated in a porcine animal model to demonstrate the ReDS accuracy in quantifying lung fluid content.

Clinical Data

Clinical studies were conducted to provide preliminary clinical performance data of the ReDS technology for the quantification of pulmonary fluid level in patients presenting various fluid content levels across the operational range (including normal to highly congested patients). No device-related adverse events were reported. The performance of ReDS in the clinical setting was consistent with the findings of the nonclinical studies.

Conclusion:

The ReDS Wearable System has the same intended use and similar indications for use, technological characteristics and principles of operation as the predicate devices. Any minor differences in the ReDS System compared to the predicate devices do not raise any new questions of safety or effectiveness. Performance tests, including bench studies, animal testing and clinical studies, have been conducted to confirm that these differences do not adversely impact safety or performance. In sum, the conclusions from the non-clinical and clinical tests demonstrate that the ReDS Wearable System performs similarly to the legally marketed predicate devices.